

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 5970/S18

APPROVAL LETTER

NDA 5-970/S-018

MAR 11 1975

Elkins-Sinn, Inc.
Attention: Ms. Thelma C. Hillbrand
2 Easterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

Reference is made to your communication dated February 4, 1975, pertaining to your new drug application for Sotradecol (sodium tetradecyl sulfate).

Your communication contained twelve copies of the final printed labeling for the drug.

We have completed our review of this submission and recommend the following:

The material submitted is being retained as part of your application for this drug.

Sincerely yours,

3/4/75-

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Margaret A. Clark, M.D.
Acting Director
Division of Surgical-Dental
Drug Products
Bureau of Drugs

cc: NYK-DO
NDA 5-970 Orig.
HFD-160
R/D by Fkuerer(HFD-160) 3/7/75
R/D init. by: CMNealey 3/10/75
MDIark 3/10/75
Final typed 3/11/75:jw

ACKNOWLEDGEMENT

Should have
been AP. changed in
ME 7/23/86